31 Partridge Ave Somerville, MA 02145 July 2, 1999

757**9** '99 JUL -9 P1:37

Dockets Management Branch (HFA-305) Food and Drug Admisnistration 5630 Fishers Lane, Room 1061 Rockville, MD 20857-0003

RE: Docket No. 98N-1265

To Whom It May Concern:

I am sending this letter as both a consumer and a provider of health care services to register my concern and strong disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act severely restricts my rights to obtain health care products from the provider of my choice. I use a compounded drug which is made in an another state by a reputable compounding pharmacy. There is no need to restrict my options by not allowing me to get this medication no matter where I live or where the pharmacy is located! I thought the role of the FDA was to be a watchdogfor my safety. This is not a safety issue and this MOU must be amended to allow me and many others access to this specialty type of health care service.

In its present form this MOU will limit the rights of pharmacists to suggest alternatives to physicians and patients. This amounts to a gag order and is completely unacceptable. As a nurse practitioner, I can prescribe medication. I consider pharmacists a vital part of the health care team. Compounding pharmacists have knowledge that I (and my physicisn colleagues) do not have about alternative medications or alternative ways to deliver a drug. I need to be able to consult with them. Again this is not a safety issue and the MOU must be amended to allow me access to important knowledge I need to provide good care to my patients.

The current MOU infringes on my rights as a consumer and a provider and it infringes on the right of these unique pharmacists to be full members of the health care team! This MOU must be amended.

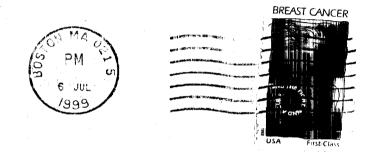
Sincerely,

athryn J. Foley RN, MS

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